

**Notice of Allowability**

Application No.

09/399,120

Examiner

Anish Gupta

Applicant(s)

MASCARENHAS, DESMOND

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5-23-07.
2. ☒ The allowed claim(s) is/are 1-10, 16, 18-21, 25-44 and 47-50.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
ANISH GUPTA  
PRIMARY EXAMINER

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kristel Schorr on 6-21-07.

The application has been amended as follows:

The specification on page 2, the first full paragraph, has been amended as follows:

A number of variant forms of IGF-I have been created which have altered binding characteristics for the IGF receptors, the insulin receptor, or IGFBP's (e.g., ~~[Ser24]~~ IGF-I (Cascieri et al. (1988) Biochemistry 27:3229-3233 and (1989) Jr. Biol. Chem. 264:2199-2202); ~~[Ala31, Leu60]~~ IGF-I, ~~[Leu24, Leu60]~~ IGF-I, and ~~[Leu24, Ala31, Leu60]~~ IGF-I (Bayne et al. (1990) J. Biol. Chem. 265:15648-15652); ~~[1-27, Gly4, 38-70]~~ IGF-I, and ~~[Leu24, 1-62]~~ IGF-I (Baxter et al. (1992) J. Biol. Chem. 267:60-65)). Additionally, International Patent Application No. WO 97/39032 discloses the use of certain variant forms of IGF-I for the treatment of conditions where increased IGF-I activity is desired, such as diabetes, osteoporosis, and the like. The variant forms of IGF-I are proposed to displace IGF-I from IGFBP, resulting in increased IGF-I activity.

### REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance:

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The claims are drawn to a method of slowing the growth rate of a tumor or slowing progression of cancer, comprising: administering an effective amount of uncomplexed null insulin like growth factor I to subject having cancer (see claims 1 and 16).

The prior art of Jameson et al. (US5473054) teach IGF-1 analogs that are effective inhibiting cell proliferation, close to 100%. The IGF analog is effective against cells including: fibroblasts, smooth muscle cells, chondrocytes and osteoblasts, hemopoietic cells of various lineages and keratinocytes. The reference states that for instance, when using the IGF-1 analog, inhibition of the growth of fibroblasts, and fibroblast-like cells, of T-lymphocytes and of epithelial cells derived from carcinoma of the prostate was observed (see col. 6, lines 15-27). The reference further states that IGF analogs have the ability to inhibit the binding of natural IGF-1 to its cognate receptor, thereby inhibiting the action of the IGF-1 receptor (see col. 3, lines 7-12 and col. 8, lines 6-15).

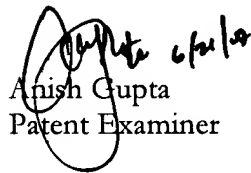
This reference does not anticipate nor render obvious the claimed invention. The Board of Appeals, stated in their decision, "as taught by the specification, a null IGF-I has amino acid sequence alterations at one or more sites in the molecule, while retaining its ability to bind to IGFBP-3, but is altered in its receptor binding and/or activating properties" (see page 6 of the BPAI decision). This definition is recited on page 5 of the specification that states "As used herein, the term 'null IGF-I' refers to IGF-I which has amino acid sequence alterations at one or more sites in the molecule. Null IGF-I retains its ability to bind IGFBP-3, but is altered in its receptor binding and/or activating properties (e.g., having little or no binding to the type 1 IGF receptor while maintaining its binding activities for the type 2 IGF receptor and the insulin receptor).". Thus, null IGF has little or no binding to the type 1 IGF receptor. Since the analogs of Jameson et al. are competitive binders to the IGF-1 receptor 1, the IGF analogs of the prior art do not fall within the

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definition of the claimed null IGF. Thus, the claimed invention is both novel and unobvious over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

  
Anish Gupta  
Patent Examiner